PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 124147x347/55 RTM	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/NZ2004/000241	International filing date *(day/month/year)* 4 October 2004	Priority date *(day/month/year)* 2 October 2003

International Patent Classification (IPC) or national classification and IPC

Int. Cl.

A61K 38/43 (2006.01) *A23K 1/165* (2006.01)

Applicant

AGRESEARCH LIMITED et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 7 sheets, as follows:
      - [X] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[ ]	Box No. VIII	Certain observations on the international application

Date of submission of the demand 10 March 2005	Date of completion of this report 23 January 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **M. Ong** Telephone No. (02) 6283 2491

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/NZ2004/000241

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

- [ ] international search (under Rules 12.3(a) and 23.1 (b))
- [ ] publication of the international application (under Rule 12.4(a))
- [ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[ ] the international application as originally filed/furnished

[X] the description:

pages **1-25, 27-29** as originally filed/furnished
pages* **26** received by this Authority on **1 February 2005** with the letter of 1 February 2005
pages* received by this Authority on with the letter of

[X] the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **30-35** received by this Authority on **16 January 2006** with the letter of 16 January 2006
pages* received by this Authority on with the letter of

[X] the drawings:

pages **1/9-9/9** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

- [ ] the description, pages
- [ ] the claims, Nos.
- [ ] the drawings, sheets/figs
- [ ] the sequence listing *(specify)*:
- [ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- [ ] the description, pages
- [ ] the claims, Nos.
- [ ] the drawings, sheets/figs
- [ ] the sequence listing *(specify)*:
- [ ] any table(s) related to the sequence listing *(specify)*:

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-36	YES
	Claims		NO
Inventive step (IS)	Claims	1-36	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-36	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1: WO 2002/019809 A
D2: LUDDEN, PA et al. J. Anim. Sci., January 2000, vol. 78(1), pages 181-187
D3: LUDDEN, PA et al. J. Anim. Sci., January 2000, vol. 78(1), pages 188-198
D4: VAREL, VH et al. J. Anim. Sci., May 1999, vol. 77(5), pages 1162-1168
D5: WHITELAW, FG et al Br. J. Nutr., September 1991, vol. 66(2), pages 209-225
D6: BRENT, BE et al. J. Anim. Sci., April 1971, vol. 32(4), pages 794-798
D7: MACKIE, RI et al. J. Anim. Sci., May 1998, vol. 76(5), pages 1331-1342

Novelty (N): Claims 1-36

The invention is directed to altering the composition of animal waste after excrement by providing a delivery device adapted to deliver internally a composition containing a urease or nitrification inhibitor such that the conversion of urea to ammonium and ammonium to nitrate in the waste is reduced or inhibited.

D1 discloses a dispensing device that is attachable to an animal, with a reservoir means that contains a urease inhibitor eg. phosphoromide nBTPT (N-n-butyl) thiophosphoric triamide (NBPT). The dispensing device is activated by the tail of the animal (see page 7, paragraph 3) and is used to add the inhibitor to the waste products of the animal such that the rate of transformation of urea to ammonium-nitrogen is reduced. Claims 1-61 are distinguished over the prior art in the use of a device that delivers the urease inhibitor internally to the animal.

D3 discloses chronic administration of NBPT to lambs and teaches that overall the urease inhibitor decreased ruminal urease activity, increased ruminal urea and decreased ruminal NH_3N concentrations. D5 teaches urease inhibitor phenylphosphoryldiamidate (PPDA) administered to sheep, resulted in a decrease in urea degradation. It was further taught that the effect of PPDA given into the rumen appeared to persist into the caecum and large intestine. However, the inhibitors have not been adapted to be in a form (eg. bolus or encapsulated), such that the inhibitors when excreted from the animal can affect the conversion of nitrogen containing compounds in the external environment.

D2 –D7 each teaches compositions of urease inhibitors. These documents do not disclose the combination of urease inhibitors and materials such as lipid-based or wax coatings or polymer matrices.

In view of the above claims 1-36 meet the criteria set out in the PCT Article 33(2) with regard to the requirement for novelty.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Inventive Step (IS): Claims 1-36

As above.

Industrial Applicability (IA) :Claims 1-36

Claims 1-36 fulfil the requirements for industrial applicability.

EXAMPLE THREE

Lysimeter study on the effect of inhibitors on N losses

A detailed lysimeter study showed that inhibitors added to urine were effective in reducing N losses, with Agrotain reducing ammonia emissions and DCD and 4MP reducing nitrate leaching and nitrous oxide (a greenhouse gas) emissions.

Undisturbed soil lysimeters (30 cm diameter x 50 cm depth) were collected from a pastoral site near Lake Taupo which had been under a cutting regime with no grazing animals for over 18 months. The soil was a Taupo sandy loam (yellow brown pumice or allophanic soil). A gap (c. 1 cm) between the side of the soil cores and the PVC lysimeter housing was filled with Vaseline to stop possible edge-flow of water or urine. The lysimeters were transferred to a lysimeter facility (near Hamilton, New Zealand) where they were buried in soil so that the soil surface in the lysimeter was at ground level. However, the lysimeter casing extended about 4 cm above the soil surface to stop any lateral surface loss.

There were five replicate lysimeters with the following treatments included: a control, urine, urine + DCD, and urine + 4MP. Urine was collected from Jersey dairy cows, stored at 4°C and applied to the lysimeters within 4 days. The urine solution was applied at 10 L/m^2 giving the equivalent of 800 kg N/ha (similar to that for a cow urine patch). For the DCD and 4MP treatments, the inhibitor compounds were dissolved in the urine prior to application to represent urine excreted from inhibitor-administered animals. Inputs in these treatments were equivalent to 1.5 g DCD/m^2 and 3.0 g 4MP/m^2.

Lysimeters were left to stabilise for several weeks after installation in the facility. Treatments were applied in May 2004. Pasture on the lysimeters was trimmed.

WHAT WE CLAIM IS:

1. A delivery device for altering the composition of animal waste,

characterised in that

the delivery device is adapted to deliver internally to an animal one or more treatment substances that can directly or indirectly affect the conversion of nitrogen containing compounds in animal waste, once the waste is excreted from the animal.

2. A delivery device as claimed in claim 1 wherein the animal waste is urine.

3. A delivery device as claimed in claim 1 or claim 2 wherein said one or more treatment substances includes a urease inhibitor.

4 A delivery device as claimed in claim 3 wherein the urease inhibitor is N-(n-butyl) thiophosphoric triamide (NBPT).

5. A delivery device as claimed in any one of claims 1 to 4 wherein said one or more treatment substances includes a nitrification inhibitor.

6 A delivery device as claimed in claim 5 wherein the nitrification inhibitor is 3,4-dimethylpyrazole phosphate (DMPP).

7 A delivery device as claimed in claim 5 wherein the nitrification inhibitor is dicyandiamide (DCD).

8. A delivery device as claimed in any one of claims 1 to 7 wherein said one or more treatment substances includes a beneficial compound which enhances the soil immobilisation of nitrogen containing compounds.

9. A delivery device as claimed in claim 8 wherein the beneficial compound enhances the growth of soil microorganisms.

10. A delivery device as claimed in claim 8 or claim 9 wherein the beneficial compounds is a complex carbon source.

11. A delivery device as claimed in any one of claims 8 to 10 wherein the material is a tannin.

12. A delivery device as claimed in any one of claims 1 to 11 wherein the animal waste acts as a carrier for said one or more treatment substances.

13. A delivery device as claimed in any one of claims 1 to 12 wherein said delivery device is administered orally to an animal.

14. A delivery device as claimed in claim 13 wherein the delivery device is a ruminal bolus.

15. A delivery device as claimed in claim 13 or claim 14 wherein the delivery device is a rumen-stable delivery device.

16. A delivery device as claimed in claim 15 wherein the delivery device includes an encapsulation system.

17. A delivery device as claimed in any one of claims 1 to 12 wherein said delivery device is inserted into an animal's bladder.

18. A delivery device as claimed in claim 17 wherein the delivery device is made of a preformed matrix.

19. A delivery device as claimed in claim 18 wherein the matrix is silicone.

20. A delivery device as claimed in anyone of claims 17 to 19 wherein the delivery device has a lower specific gravity than urine.

21. A delivery device as claimed in any one of claims 1 to 20 wherein one or more treatment substances are contained within the inner core of the delivery device.

22. A delivery device as claimed in any one of claims 1 to 20 wherein the delivery device is impregnated with said one or more treatment substances.

23. A delivery device as claimed in any one of claims 1 to 22 wherein said one or more treatment substances are delivered by diffusion from the delivery device.

24. A delivery device as claimed in any one of claims 1 to 22 wherein said one or more treatment substances are delivered through dissolution of the delivery device.

25. A delivery device as claimed in any one of claims 1 to 24 wherein the delivery device is configured to allow for sustained, slow release of said one or more treatment substances.

26. A delivery device as claimed in any one of claims 1 to 25 wherein the delivery device includes an electrochemical cell.

27. The use of one or more treatment substances in the manufacture of a delivery device as claimed in any one of claims 1 to 26 for delivering said one or more treatment substances internally to an animal to directly or indirectly affect the conversion of nitrogen containing compounds in animal waste, once the waste is excreted from the animal.

28. A method of altering the composition of animal waste,

characterised by the step of

introducing internally to an animal one or more treatment substances that can directly or indirectly affect the conversion of nitrogen containing compounds in animal waste, once the waste has been excreted from the animal.

29. A method as claimed in claim 28 wherein said one or more treatment substances are introduced by way of a delivery device as described in any one of claims 1 to 26.

30. A method as claimed in claim 28 or claim 29 wherein said one or more treatment substances are introduced to the animal over an extended time period.

31. A method for decreasing the amount of convertible nitrogen released from an animal

characterised by the step of

administering internally to the animal an effective amount of a treatment substance capable of directly or indirectly affect the conversion of nitrogen containing compounds in animal waste, once the waste is excreted from the animal.

32. A composition for incorporation into a delivery device as claimed in any one of claims 1 to 26 for introduction to an animal to alter the composition of animal waste,

characterised in that the composition includes

one or more treatment substances for directly or indirectly affecting the conversion of nitrogen containing compounds in animal waste, and

material to ensure the conversion is affected once the animal waste is excreted from the animal.

33. A composition as claimed in claim 32 wherein the material is selected from a

list including lipid-based coatings, wax coatings and polymer matrices

34. A delivery device substantially as described herein with reference to and as illustrated by the accompanying description and drawings.

35. A method of altering the composition of animal waste substantially as described herein with reference to and as illustrated by the accompanying description and drawings.

36. A composition substantially as described herein with reference to and as illustrated by the accompanying description and drawings.